

**QUALITY ASSURANCE ANNUAL REPORT AND WORK PLAN**

**QUALITY STAFF**

**FY 2000**

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## QUALITY STAFF'S ANNUAL REPORT FOR FY 2000

### 1.0 Quality Management Resources

1.1	Total FTE's in Quality Staff	17
1.2	Total FTE's for management of QA and QC activities	13
1.3	FTE's in QA and QC support activities	2
1.4	Total Contractor FTE's	6.75
1.5	Total FTE's for non-technical QA and QC support activities	2
1.6	Total QA supporting funds, not including travel funds or training (in thousands of dollars)	1,400
1.7	Total travel funds used for QA activities (in thousands of dollars)	90
1.8	Total funds used for QA and QC training, including development of training courses (in thousands of dollars)	675
	Total Number of individuals trained (approximate)	450

The above resources were adequate in FY 2000 to meet our objectives. However, the number of FTEs that is now spent devoted to the administrative requirements of the Office of Environmental Information may be inadequate.

### 2.0 Training

- Training Needs Assessment:** The Quality Staff conducts Quality Systems training needs assessments to identify unmet training needs that fall within the scope of the mission of the Quality Staff. It is also intended to provide a consensus of what training areas are important to our stakeholders. A needs assessment survey was conducted in December 1999, and it is anticipated that these will be done every two to three years. The survey results identified unmet training needs in the application of Data Quality Objectives, Data Quality Assessment, and Statistics. The survey also indicated a need for easy access to training materials. In response to these needs, the Quality Staff is in the process of developing a course in Data Quality Assessment and Statistics. Additional courses in Data Quality Objectives application are planned. To provide better access to training materials, the Quality Staff has posted five training courses on the Quality Staff web page, complete with facilitation guides and exercises.

- **Training Conferences:** The Quality Staff offers two major Quality Systems training events each year. This includes the Annual Summer Training Conference, and a full day of training at the National Annual Conference on Managing Environmental Quality Systems. The Quality Staff provides training to other Agency organizations on a requested/time available basis. The courses presented and number of attendees is listed in the tables below.

**19<sup>th</sup> Annual Conference on Managing Environmental Quality Systems  
April 3-7, 2000; 325 total participants (no demographic breakdown available)**

<b>Course Name</b>	<b>Supplier</b>	<b>Attendance (From outside Quality Staff)</b>
Preparation and Review of QA Project Plans	Quality Staff	80
Introduction to Quality System Audits	Quality Staff	68
Introduction to DQOs	Quality Staff	63
Quality Management Plan Overview	Quality Staff	65
Introduction to EPA Quality Systems	Quality Staff	45
GIS for QA Professionals	Quality Staff	52

**Summer Training Conference, August 7-10, 2000  
148 total participants (23% Indian Tribes and Nations, 4% private sector,  
2% other Federal agencies, and 71% EPA)**

<b>Course Name</b>	<b>Supplier</b>	<b>Attendance (From outside Quality Staff)</b>
Introduction to EPA Quality System Requirements	Quality Staff	45
Overview of EPA Quality System Requirements for Managers	Quality Staff	23
Introduction to DQOs	Quality Staff	42
Overview of Quality Management Plan Requirements	Quality Staff	60
Introduction to Quality Systems Audits	Quality Staff	66

Basic Statistics for QA Professionals	Quality Staff	60 (pilot course)
Quality Assurance Project Plan Workshop	Quality Staff	60
Integrating QA into Project Development	Quality Staff	26

In all cases, course evaluations indicate that course objectives were met. For the summer training conference, we also conducted follow-up surveys to determine the impact of our training events. This information will be used to refine training efforts and materials.

- **NELAC/NELAP Support:** The Quality Staff also provides limited organizational and management support to the National Environmental Laboratory Accreditation Program (NELAP). The Quality Staff developed and provided NELAC 101 orientation presentations at several conferences, e.g., AFCEE on Remedial Process Optimization; and the NELAC VI National Meeting. The Quality Staff also provided NELAC Accrediting Authority Assessor training to state and Federal personnel.

### 3.0 Management Accomplishments

#### 3.1 *Innovative Management Practices:*

- **Strategic Plan:** The Quality Staff has developed a Strategic Plan to guide its activities over the next five years. The Plan will be formally released during FY 2002.
- **Quality Requirements in Contracts:** The Contract Management Manual is being revised and updated. A Federal Register Notice to remove 48 CFR §1546 is in the system, but put on hold for 60 days due to requirements of the new administration. The Federal Register Notice to remove EPA AR 1546.2 was published on December 20, 2000, with an effective date of March 20, 2001.
- **Quality Requirements in Assistance Regulations:** Information Collection Request (ICR) Number 0866.06 for quality assurance documentation is awaiting OMB approval. It has already been extended well beyond its August expiration date. This ICR allows for the collection of QA documentation that conforms with EPA requirements through national consensus standards from holders of assistance agreements under 40 CFR §30 and §31. These are awarded to State, Local, and Tribal governments, and non-profit organizations.
- **Laboratory Audits:** The Quality Staff participated in four Technical Systems Audits of Agency Regional laboratories in FY 2000. In FY 2001 we will continue the effort that began with the Regional laboratories, and will coordinate and lead evaluation of EPA's National Program and

Office of Research and Development laboratories. This effort will focus on the laboratories' production of data of known and documented quality. This will result in both individual audit reports to each laboratory and summary of findings across laboratories. The Quality Staff currently has a work plan in place to communicate and coordinate audit activities with the laboratories, and to provide options for training to subject matter experts who will serve as laboratory auditors.

### **3.2    *Technical Assistance***

- **Outreach/Consulting:** The Quality Staff provides technical assistance on quality assurance, quality control, quality management plan development, and statistics. Two FTE's are spent on technical assistance. The Quality Staff offers assistance to EPA Program Offices/Laboratories, EPA Regions, States, Tribes and private organizations.
- **Workgroups/Programs:**

The Quality Staff participate in the following EPA workgroups and/or programs:

- S    Agency-wide Council for Regulatory Environmental Modeling
- S    Data Set Data Quality Indicators
- S    Diversity Action Plan Workgroup
- S    Environmental Information Management Systems (EIMS)
- S    EPA Voluntary Standards Network (VSN) for ISO and ANSI Standards
- S    Geographic Information Systems and Geographic Information Systems Quality Assurance Workgroups.
- S    Graded Approach Workgroup
- S    Information Technology QA Guidance development
- S    OEI Best Data Practices Workgroup
- S    OEI/Geospatial Data Workgroup
- S    OEI Information Plan
- S    OEI Web Workgroup
- S    OEI Data Quality Strategic Plan
- S    OEI Budget Workgroup
- S    OEI product Review Workgroup
- S    Peer Review Advisory Group
- S    Reinventing Environmental Information Work group
- S    Science Inventory Workgroup
- S    Screening Methods for Drinking Water Compliance
- S    Standard Methods for the Examination of Water and Wastewater
- S    Statistical Policy Advisory Committee

The Quality Staff also participate in the following external workgroups and/or programs:

- S Inter-Governmental Data Quality Task Force (IDQTF).
- S Metrics policy (e.g., EPA Order 1000.1)
- S NELAC Basic Assessor Training Course Subcommittee
- S NELAC ISO 17025 Workgroup
- S NELAC On-site Assessment Committee
- S NELAC Quality System Committee
- S NELAC Quality System Microbiology Subcommittee
- S U.S. Technical Advisory Group to ISO Technical Committee (TC) 176 on Quality Management
- S U.S. Technical Advisory Group to ISO Technical Committee (TC) 207 on Environmental Management

### **3.3 *New/Revised QA Guidance***

The Quality Staff issued six documents; released four documents for peer review; continued the development of six documents, and started on six new documents. Appendix B describes the documents released in FY 2000 in more detail.

- **Documents Issued:**

- S EPA Order 5360.1.A1, EPA Quality Manual for Environmental Programs - May 2000
- S EPA Order 5360.1.A2, Policy and Program requirements for the Mandatory Agency-wide Quality Systems - May 2000
- S Guidance for the Data Quality Objectives Process for Hazardous Waste Sites (G-4HW) - January 2000
- S Guidance on Technical Audits and Related Assessments (G-7) - January 2000
- S Guidance for Data Quality Assessment (G-9) - August 2000
- S Guidance for the DQO Process (G-4) - September 2000 (5-year update)

- **Guidance Peer Reviewed:**

- S Overview of the EPA Quality System
- S Guidance on Satisfying EPA Quality System Requirements for STAR Grants (G-1STAR)
- S Guidance on Developing a QA Training Program (G-10)
- S Data Quality Objectives Decision Errors Feasibility Trails Software

- **Guidance Development Continued:**

- S Re-issue of Guidance for Standard Operating Procedures (G-6)
- S Re-issue of Guidance for QA Project Plans (G-5)
- S Guidance on Systematic Planning (G-4A)
- S Guidance on Data Quality Indicators (G-5I)
- S Sampling Designs for QA Project Plans (G-5S)
- S Guidance on Data Validation and Verification (G-8)

- **New Guidance Started:**

- S Guidance on EPA's Quality System Audits (G-3Q)
- S QA Project Plans for Geospatial Data (G-5G)
- S QA Project Plans for Models (G-5M)
- S Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation (G-11)
- S Guidance on Assessing Secondary Data
- S Guidance on Developing a Quality System (G-2)

### **3.4 Awards**

Gary L. Johnson was awarded the Gene Basile Award in August 2000 by the American Society for Quality's Energy and Environmental Division. This award is the highest recognition given by the Energy and Environmental Division.

## **4.0 Management Assessments of the Approved Quality System**

### **4.1 Summary of Internal Management Assessments**

In all of the Management Systems Assessments/Quality Systems Assessments conducted this year, it was found that several organizations had well designed quality systems with generally effective implementation of quality practices. However, the majority of organizations assessed did not conform to EPA requirements and policy. In most cases:

1. OMP's were expired and did not reflect actual practices;
2. The independence of the QA Manager function is questionable and does not conform to EPA Order 5360.1.A2;
3. Procurement and financial assistance processes do not comply with Federal regulations for quality requirements and EPA policy requirements; and

4. Resources appeared to be insufficient to support the organizations/programs. Appendix C provides a summary of the state of the Agency's Quality systems.

The table below provides a summary of Management Assessments performed in FY 2000:

Organization	Dates of Review
Office of Science and Technology (OW)	February 29-March 2, 2000
Office of Wastewater Management (OW)	September 19-21, 2000
National Risk Management Research Laboratory (ORD)	March 20-23, 2000
National Center for Environmental Research (ORD)	August 29-30, 2000
National Exposure Research Laboratory (ORD)	August 14-18, 2000
Office of Radiation and Indoor Air (OAR)	June 13-14, 2000; June 19-20, 2000
Gulf of Mexico Program Office	June 13-15, 2000
Region 1	January 10-14, 2000
Region 4	February 7-11, 2000

#### **4.2     *Summary of External Management Assessments***

No external management assessments were conducted in FY 2000. Our external management assessments are scheduled to begin in FY 2001.

## QUALITY STAFF'S WORK PLAN FY 2001

### 1.0 Quality Management Resources

1.1	FTE for management of QA and QC activities	13
1.2	FTE for QA and QC support activities	2
1.3	FTE from Contractors	6.75
1.4	FTEs for non-technical QA and QC support activities	2
1.5	Total QA supporting funds, not including travel funds or training (in thousands of dollars)	800
1.6	Travel Funds for QA activities (in thousands of dollars)	100
1.7	Funds for QA and QC training, including development of training courses (in thousands of dollars)	300

### 2.0 Activities

#### **Laboratory Quality System Practices at Program Office and Research and Development**

**laboratories:** The Quality Staff has been assigned the responsibility for leading technical systems audits of these EPA operated laboratories. There are more than 20 laboratory Facilities/Divisions in this community.

#### **2.1 Planned QA and QC Activities:**

- Remove 48 CFR §1546
- Establish workgroup to develop and propose changes to Contracts Management Manual
- Issue first performance measures report on the Agency's Quality System
- Review approximately 20 QMPs expected in FY01
- Conduct management assessments of nine Agency Organizations
- Office of Air and Radiation, Office of Atmospheric Programs

S Office of Enforcement and Compliance, Federal Facilities Enforcement Office  
 S Office of Enforcement and Compliance, Office of Compliance  
 S Office of Enforcement and Compliance, Office of Regulatory Enforcement

- S Office of Enforcement and Compliance, Office of Site Remediation Enforcement
  - S Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs
  - S Office of Enforcement and Compliance, Office of Pollution Prevention and Toxics
  - S Office of Solid Waste and Emergency Response, Office of Solid Waste
  - S Office of Solid Waste and Emergency Response, Office of Underground Storage Tanks
  - S Office of Solid Waste and Emergency Response, Office of Emergency and Remedial Response, Remedial and Non-Remedial Program
  - S Region 3
  - S Region 5
  - S Region 6
  - S Region 10
- Conduct 20th Annual Conference for 300 individuals
  - Conduct Annual Training Conference for 100 individuals
  - Provide 6 training events
  - Re-compete vehicle that provides training and consulting support
  - Design new training courses to meet documented training needs:
    - S Peer Review training materials
    - S Data Quality Indicators course
    - S Data Quality Assessment
    - S Minimum Detection Issues course
    - S Data Interpretation and Statistical Analysis course
  - Issue the following documents:
    - S Managing the EPA Quality System
    - S Data Quality Objective Decision Error Feasibility Trails (DQO/DEFT) (G-4D)
    - S Re-issue Guidance for Standard Operating Procedures (G-6)
    - S Data Quality Evaluation Statistical Toolbox (Data QUEST) (G-9D)
    - S Guidance on Developing a QA Training Program (G-10)
    - S Requirements for Quality Management Plans (R-2)
    - S Requirements for Quality Assurance Project Plans (R-5)
  - Provide Peer Review for:
    - S Reissue of the Guidance for QA Project Plans (G-5)

- S Guidance on EPA's Quality System Audits (G-3Q)
  - S Guidance on Systematic Planning (G-4A)
  - S Guidance on Data Quality Indicators (G-5I)
  - S QA Project Plans for Models (G-5M)
  - S Sampling Designs for QA Project Plans (G-5S)
  - S Guidance on Data Validation and Verification (G-8)
- Continue development of:
    - S Guidance on Assessing Secondary Data
    - S Graded Approach Guidance
    - S Guidance on Developing a Quality System (G-2)
    - S Quality Assurance Project Plans for Geospatial Data (G-5G)
    - S Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation (G-11)
    - S Guidance on Surveillance (G-75)
  - Develop Operating Plans for Quality Staff's seven major activities
  - Beta Version of Agency-wide Quality System Tracking System
  - Create a series of Quality Fact Sheets
  - Continue conducting conference calls with major constituency groups

## **2.2 *Corrective Action from Prior Management Systems Reviews (MSR's)***

No MSR's were conducted of the Quality Staff during FY 2000.

## Appendix A

### FY 2000 Quality Staff Conferences/Events

- Event:** The 19<sup>th</sup> Annual National Conference on Managing Quality Systems, Albuquerque NM
- Contact:** Nancy Wentworth, Director, Quality Staff, Washington DC
- Attendance:** Over 300 individuals participated in the conference, representing EPA, other Federal agencies, State, local and Tribal governments, private industry, and academia.
- Purpose:** EPA sponsors a national conference on managing quality systems for environmental programs every year. This conference is a national forum for disseminating and exchanging information on managing the quality of environmental data; discussion and action on issues of national concern; training; and technical presentations. The theme of the 19<sup>th</sup> Annual National Conference was “EPA Initiatives in Quality Management: Quality and Environmental Information.” New training offered at this conference included Quality Management Plans; Quality Assurance Project Plans, Quality Systems Audits; and GIS for QA Professionals. Technical sessions covered such topics as QA and the Law, Quality-Related Issues for Laboratories, and Systematic Planning. Copies of all available session papers are posted on the Quality Staff Website.
- Date:** April 3-7, 2000
- 
- Event:** Quality Systems Training Conference 2000, Chicago IL
- Contact:** Diann Sims, Quality Staff, Washington DC
- Attendance:** OEI employees and invited guests
- Purpose:** During the four-day conference, 148 participants received training. These included quality management professionals from EPA, State, local and Tribal governments, the private sector, and other Federal agencies. Training staff consisted of six Quality Staff members and two guest instructors. Eight training courses, ranging from two-hour overviews to full-day workshops, were offered.
- Date:** August 7-10, 2000
- Comments:** The conference was held in the training center of the Metcalf Building, which houses Region 5 offices. Conference space and audio-visual equipment was provided by Region 5.

## Appendix B

### FY 2000 Quality Staff Published/Printed Electronic Products

- Title:** **Guidance on Technical Audits and Related Assessments for Environmental Data Operations**
- Contact:** Gary Johnson, Quality Staff, Research Triangle Park, NC
- Audience:** Internal and external audiences
- Purpose:** To provide guidance on general auditing principles and practices that may be applied to environmental data operations, and to provide guidance on several types of audits and assessments that may be used. Technical audits and assessments are important tools to help decision makers obtain the type and quality of data needed for an intended purpose.
- Release Date:** January 2000
- Comments:** The document was distributed to personnel in EPA, other Federal agencies, State, local and Tribal governments, and the private sector. The document was also posted on the Quality Staff Website.
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- Title:** **Guidance on the Data Quality Objectives Process for Hazardous Waste Site Investigations**
- Contact:** John Warren, Quality Staff, Washington DC
- Audience:** Internal and external audiences
- Purpose:** To provide guidance on applying the Data Quality Objectives Process, a systematic planning process, to hazardous waste site investigations. EPA requires the use of a systematic planning process for all environmental data collection efforts. The Data Quality Objectives Process is EPA's preferred process for selecting between two opposing conditions.
- Release Date:** January 2000
- Comments:** The document was distributed to personnel in EPA, other Federal agencies, State, local and Tribal governments, and the private sector. The document was also posted on the Quality Staff Website.
- 
- Titles:** **EPA Order 5360.1 A2, Policy and Program Requirements for the Mandatory Agency-wide Quality System; EPA Manual 5360 A1, EPA Quality Manual for Environmental Programs**
- Contact:** Nancy Wentworth, Director, Quality Staff; Brenda Young, Quality Staff, Washington DC
- Audience:** Internal audience
- Purpose:** These two policy documents were revised to reflect organizational changes to the EPA Quality System resulting from creation of the Office of Environmental

Information, and to reflect minor changes to the Agency-wide Quality System since July 1998.

**Release Date:** May 2000

**Comments:** The document was distributed to EPA personnel and posted on the Internet for other interested individuals.

**Title:** **Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA00 Version)**

**Contact:** John Warren, Quality Staff, Washington DC

**Audience:** Internal and external audiences

**Purpose:** To provide guidance on determining whether the type, quantity and quality of data needed to support Agency decisions have been achieved. This is an update to existing guidance that incorporates new statistical tools.

**Release Date:** September 2000

**Comments:** The document was distributed to personnel in EPA, other Federal agencies, State, local and Tribal governments, and the private sector. The document was also posted on the Quality Staff website.

**Title:** **Guidance on the Data Quality Objectives Process**

**Contact:** John Warren, Quality Staff, Washington DC

**Audience:** Internal and external audiences

**Purpose:** To provide guidance on planning and/or use of environmental data for decision making. The Data Quality Objectives Process is a systematic planning process used to clarify study objectives, define the appropriate type of data needed, and specify tolerable levels of potential decision errors, in order to establish a basis for the quality and quantity of data needed to support decisions. The use of a systematic planning process is required by the EPA. This is an update to an existing guidance, which had expired per EPA policy (EPA Manual 5360).

**Release Date:** January 2000

**Comments:** The document was distributed to personnel in EPA, other Federal agencies, State, local and Tribal governments, and the private sector. The document was also posted on the Quality Staff website.

**Title:** **Guidance for Developing a Quality Assurance Training Program**

**Contact:** Diann Sims, Quality Staff, Washington DC

**Audience:** Internal and external audiences

**Purpose:** To assist EPA in developing a quality assurance training program, by outlining a process for performing a training needs assessment and developing a training plan.

**Release Date:** January 2000

**Comments:** Peer review of this document was initiated in April 2000.

**Title:** **Guidance on Satisfying EPA Quality System Requirements for STAR Grants**

**Contact:** Gary Johnson, Quality Staff, Research Triangle Park, NC

**Audience:** Internal and external audiences

**Purpose:** To provide guidance on meeting EPA's requirements for quality assurance (QA) and quality control (QC), for applicants to the Science to Achieve Results (STAR) program. Applicants for financial assistance under the STAR grants program may use this document to complete the QA and QC requirements based on the principle of "graded approach," in order to determine appropriate QA and QC practices needed for a particular research proposal.

**Release Date:** This document will be issued by the National Center for Environmental Research.

**Comments:** Peer review of this document was initiated in February 2000.

  

**Title:** **Data Quality Objectives Decision Errors Feasibility Trials Software**

**Contact:** Brenda Young, Quality Staff, Washington DC

**Audience:** Internal and external audiences

**Purpose:** To provide project managers and technical staff with the ability to estimate their decision error limits when planning the collection of environmental data. This software is Microsoft Windows-based, and considers several different statistical parameters and sampling designs.

**Release Date:** March 2000

**Comments:** Peer review of this software was initiated in September 2000.